

**REMARKS/ARGUMENTS**

Claims 21 to 47 are currently pending. Claims 1 to 20 were previously cancelled. Claims 21 and 31 are amended. Claims 42 to 47 are new. The new claims as well as the amendments to the previously existing claims are fully supported by the original specification.

**Rejections of claims 21 to 39 under 35 U.S.C. §103(a) as being unpatentable over Hunter et al. (US 6,391,337) in view of Schmitz et al. (US 6,079,968) and Valentine (US 4,684, 534).**

The rejection under 103(a) is based on the assumption that the skilled artisan would have easily combined the teachings from the Hunter et al. patent with those of the Schmitz et al. patent and with those of the Valentine et al. patent. Applicants respectfully traverse this rejection and request reconsideration for the following reasons.

First, in contrast to the Hunter et al. patent, which simply teaches the preparation of a coated acetaminophen tablet by direct compression, claim 21 of the present patent application teaches a directly compressible tablet adapted to disintegrate in the mouth on contact with saliva in less than 30 seconds forming an easy-to-swallow suspension and having a friability of less than 1%, said tablet comprising a dry mixture of coated microcrystals or microgranules of an active substance and excipients including at least a disintegrating agent, a soluble agent with binding properties, and a lubricating agent in powder form, wherein more than half of the lubricating agent is distributed on the tablet surface.

In that respect, the Applicant respectfully submits that it is far from obvious that one of ordinary skill would have used the Schmitz *et al.* document in combination with the Hunter *et al.* document (Valentine being relied upon only as a teaching reference), to solve the problem of the present patent application: reducing tablet friability when removing said tablets from the blisters in which they are packed. Furthermore, it is the Applicant's submission that there was no incentive at the time for the skilled artisan to expressly apply the teachings from the Schmitz *et al.* patent to the very tablets described in the Hunter *et al.* patent for the reasons below.

In fact, since the Hunter *et al.* tablet comprises a coating selected from the group consisting of a hydrophobic polymer, an enteric coating material, a hydrophilic material, acetaminophen and mixtures thereof (claim 1), the coating in itself, according to Mr. Edouard Gendrot's Declaration under Rule 132 (unexecuted version attached with executed version to follow), eliminates the risk of friability of the tablet when they are removed from the blisters in which they are packed, thus making it unnecessary to reduce its friability. In retrospect, as none of the cited prior art even discussed tablet friability, Applicant submits that there was absolutely no incentive (nor suggestion), to add such a lubricant at the outer surface of the tablet. In contrast to the tablet of the present application which contains no coating, because the Hunter *et al.* tablet is in fact coated and thus not confronted with a friability problem as it is the case in the present patent application, it is rather unlikely that the combination of the Hunter *et al.* patent with the Schmitz *et al.* patent would even have been thought of and/or attempted.

In other words, since the tablets of the present invention are not coated, the friability of the tablet becomes a key issue. Surprisingly and unexpectedly, the Applicant has found that by adding more than half of the lubricating agent onto the tablet's surface, this reduces the friability to less than 1% and preferably to less than 0.5%. On this issue, Applicant would like to draw the Examiner's attention towards the enclosed Declaration under Rule 132 by Mr. Edouard Gendrot as well as to the related Test Report. In this particular test, two series of tablets (C1 and C2) were prepared using the same ingredients as in the present patent application. However, tablets C1 were prepared by incorporating the magnesium stearate with the other excipients before compression, while tablets C2 were prepared by spraying the magnesium stearate on the punches instead of incorporating the magnesium stearate inside the tablets. The results show that the tablets C1, in which the lubricant (i.e. magnesium stearate) was mixed with the other ingredients before compression, have an increased friability level compared to the tablets C2, in which the lubricant was applied on the external surface of the punches - all this, while still increasing the disintegration time of the tablet.

Finally, should there have been an incentive to combine the cited references, Applicants respectfully submit that said combination would never have amounted to the present tablet, since in contrast to the Hunter *et al.* tablet, the tablet of the present invention is structurally different in that it is not coated. Again, the fact that the tablets of the present invention are not coated renders them more susceptible to friability - a problem which was surprisingly resolved in the present patent

application by the addition of more than half of the lubricating agent at the outer surface of the tablets.

Accordingly, reconsideration and withdrawal of the obviousness rejection of claims 21-39 are respectfully requested.

**Rejections of claims 40 and 41 under 35 U.S.C. §103(a) as being unpatentable over Hunter et al. (US 6,391,337) in view of Schmitz et al. (US 6,079,968).**

The Applicant submits that since claims 21 and 31 are non-obvious in view of the above, then it follows that claims 40 and 41, which are respectively dependent upon claims 31 and 21, are also non-obvious for the same reasons.

Accordingly, reconsideration and withdrawal of the obviousness rejection of claims 40 and 41 are respectfully requested.

In view of the above amendments and comments, it is considered that the application is now in proper form for allowance.

Favorable consideration and prompt allowance of the above claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact

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Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

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